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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/480,544	01/10/00	KENTEN J	0039096-0030

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EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	2
DATE MAILED:	04/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/480,544	Kenten et al.
Examiner	**Group Art Unit**
Arun Chakrabarti	1655

☒ Responsive to communication(s) filed on *Jan 10, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-20* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. This application appears to be a division of Application No. 08/474,927, filed 0n June 7, 1995. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite over the recitation of the phrase "siad". It is not clear whether a particular and specific nucleic acid is claimed or it just means "above mentioned".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 15, 17, 18 and 20 are rejected under 35 U.S.C. 102 (e) as anticipated by Earle et al (U.S. Patent 5,925,518) (July 20, 1999).

Earle et al teaches a process for the detection and quantitative measurement of amplified products (Abstract, Figure 2 and Table 2) comprising the steps of :

(a) amplifying a sample nucleic acid (either known or unknown) under conditions to generate amplified product (Example 1, column 8, line 57 to column 9, line 10 and column 8, lines 25-33);

(b) mixing the amplified product with two binding species comprising

(I) an ECL labeled binding species which interacts with a trimolecular complex with the amplified nucleic acid and bivalent binding species (column 8, lines 10-17and Example 1, column 10, lines 7-10);

(ii) a bivalent binding species which interacts with a trimolecular complex with the amplified nucleic acid and ECL labeled binding species (Example 1, column 10, lines 7-10 and column 8, lines 10-17);

to form a binding complex reaction;

c) incubating the binding complex reaction under conditions which allow the formation of a trimolecular complex of amplified product, ECL labeled binding species, and bivalent binding species (Example 1, column 10, lines 12-14);

(d) capturing the trimolecular complex via the bivalent binding species (Example 1, column 10, lines 7-10 and column 8, lines 10-17); and

(e) quantitating ECL label captured on the solid phase (Example 1, column 10, lines 12-19 and Figure 2, Table 2).

Earle et al teaches a process wherein the binding species is selected from the group consisting of DNA:RNA (column 8, lines 1-25).

Earle et al teaches a process wherein the sample is selected from amplified nucleic acids (Example 1, column 10, lines 5-7).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 15-20 are rejected under 35 U.S.C. 102 (e) over Earle et al (U.S. Patent 5,925,518) (July 20, 1999) in view of Walker (U.S. Patent 5,455,166) (October 3, 1995).

Earle et al teaches the method of claims 15, 17, 18 and 20 as described above.

Earle et al does not teach the process wherein the amplification conditions are isothermal.

Walker teaches the process wherein the amplification conditions are isothermal (Abstract and Example 2, column 12, lines 3-6).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the isothermal amplification model of Walker in the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. sinceWalker et al. states , "This invention relates a nucleic acid target amplification and detection method which operates at a single

temperature (abstract, lines 1-2)". An ordinary practitioner would have been motivated to combine the isothermal amplification model of Walker in the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. in order to achieve the express advantages noted by Walker of an amplification system which operates at a single temperature

8. Claims 1-14 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Malek et al. (U.S. Patent 5,130,238) (July 14, 1992) in view of Earle et al (U.S. Patent 5,925,518) (July 20, 1999).

Malek et al teaches a process for the detection of a specific nucleic acid sequence (Abstract and Figure 1A), comprising the steps of:

(a) providing a single reaction medium containing reagents (claim 1, column 22, lines 57-58) comprising

(I) a first oligonucleotide primer (claim 1, column 22, line 59) ,

(ii) a second oligonucleotide primer comprising an antisense sequence of a promoter (claim 1, column 22, lines 60-61),

(iii) a DNA-directed RNA polymerase that recognizes the promoter (claim 1, column 22, lines 62-63),

(iv) an RNA-directed DNA polymerase (claim 1, column 22, lines 64),

(v) a DNA-directed DNA polymerase (claim 1, column 22, lines 65),

(vi) a ribonuclease that hydrolyzes RNA of an RNA-DNA hybrid without hydrolyzing single or double-stranded DNA (claim 1, column 22, lines 66-68),

(b) Providing in the reaction medium RNA comprising an RNA first-template which comprises the specific nucleic acid sequence or a sequence complementary to the specific nucleic acid sequence, under conditions such that a cycle ensues (claim 1, column 23, lines 4-8) wherein

(I) the first oligonucleotide primer hybridizes to the RNA first template (claim 1, column 23, lines 9-10),

(ii) the RNA-directed DNA polymerase uses the RNA first template to synthesize a DNA second template by extension of the first oligonucleotide primer and thereby forms an RNA-DNA hybrid intermediate (claim 1, column 23, lines 11-15),

(iii) the ribonuclease hydrolyses RNA which comprises the RNA-DNA hybrid intermediate (claim 1, column 23, lines 16-17),

(iv) the second oligonucleotide primer hybridizes to the DNA second template (claim 1, column 23, lines 18-19),

(v) the DNA-directed DNA polymerase uses the second oligonucleotide primer as template to synthesize the promoter by extension of the DNA second template (claim 1, column 23, lines 20-23),

(vi) the DNA-directed RNA polymerase recognizes the promoter and transcribes the second template, thereby providing copies of the RNA first template (claim 1, column 23, lines 24-27); and thereafter

c) Maintaining the conditions for a time sufficient to achieve a desired amplification of the specific nucleic acid sequence (claim 1, column 23, lines 28-31).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium single-stranded DNA which comprises an antisense sequence of the promoter (Claim 10, lines 59-65).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium and RNA-DNA hybrid comprising the single-stranded DNA, such that the ribonuclease hydrolyzes RNA which comprises the RNA-DNA hybrid (Claim 5, column 24, lines 25-29).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium single-stranded DNA which comprises the DNA second template, such that

(I) the second oligonucleotide primer hybridizes to the single-stranded DNA (claim 6, column 24, lines 34-35),

(ii) the DNA-directed DNA polymerase uses the second oligonucleotide primer as template to synthesize the promoter by extension of the DNA second template (claim 6, column 24, lines 36-39), and

(iii) the DNA-directed RNA polymerase recognizes the promoter and transcribes the DNA second template, thereby providing copies of the RNA first template (claim 6, column 24, lines 40-43).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium a DNA comprising the promoter, such that the DNA-directed RNA polymerase transcribes the DNA, thereby synthesizing the single-stranded RNA (claim 8, column 24, lines 49-53).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium a DNA comprising the promoter, such that the DNA-directed RNA polymerase transcribes the DNA, thereby synthesizing the single-stranded RNA (claim 9, column 24, lines 54-58).

Malek et al teaches a process wherein the RNA-directed DNA polymerase is a retrovirus reverse transcriptase (claim 30, column 26, lines 4-6).

Malek et al teaches a process wherein the DNA-directed DNA polymerase lacks exonuclease activity (claim 33, column 26, lines 13-15).

Malek et al teaches a process wherein all DNA polymerases in the reaction medium lack exonuclease and DNA endonuclease activity (claim 34, column 26, lines 16-18).

Malek et al teaches a process wherein the DNA-directed DNA polymerase is DNA polymerase alpha or DNA polymerase beta.

Malek et al does not teach the addition of;

(I) at least one probe sequence complementary to the RNA first template labeled with an electrochemiluminescent species,

(ii) at least one second capture probe sequence complementary to the RNA first template labeled with a binding species,

(iii) a bead coated with a complementary binding species to the second probe sequence; and thereafter

(d) providing conditions of temperature and buffer to allow the hybridization of the probes to the first RNA template and the binding of the binding species on the second capture probe with the complementary binding species on the bead to form a bead bound complex; and then

(e) detecting the bead bound complex using the electrochemiluminescent species.

Earle et al teaches the addition of;

(I) at least one probe sequence complementary to the RNA first template labeled with an electrochemiluminescent species (Example 1, column 10, lines 5-12 and column 7, line 31 to column 8, line 17),

(ii) at least one second capture probe sequence complementary to the RNA first template labeled with a binding species (Example 1, column 10, lines 7-12 and column 7, line 31 to column 8, line 17)

(iii) a bead coated with a complementary binding species to the second probe sequence (Example 1, column 10, lines 7-10); and thereafter

(d) providing conditions of temperature and buffer to allow the hybridization of the probes to the first RNA template and the binding of the binding species on the second capture probe with the complementary binding species on the bead to form a bead bound complex (Example 1, column 10, lines 12-14); and then

(e) detecting the bead bound complex using the electrochemiluminescent species.(Example 1, column 10, lines 12-19 and Figure 2, Table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. in the enhanced nucleic acid amplification method of Malek et al. since Earle et al. states , "Any of these methods could significantly reduce the time required for diagnosis of infection with M. Tuberculosis, perhaps to as little as one day(Column 1, lines 54-56)". An ordinary practitioner would have been motivated to combine the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. in the enhanced nucleic acid amplification method of Malek et al in order to achieve the express advantages noted by Earle et al.of a system which could significantly reduce the time required for diagnosis of infection perhaps to as little as one day.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

April 6, 2000

JEFFREY FREDMAN
PRIMARY EXAMINER